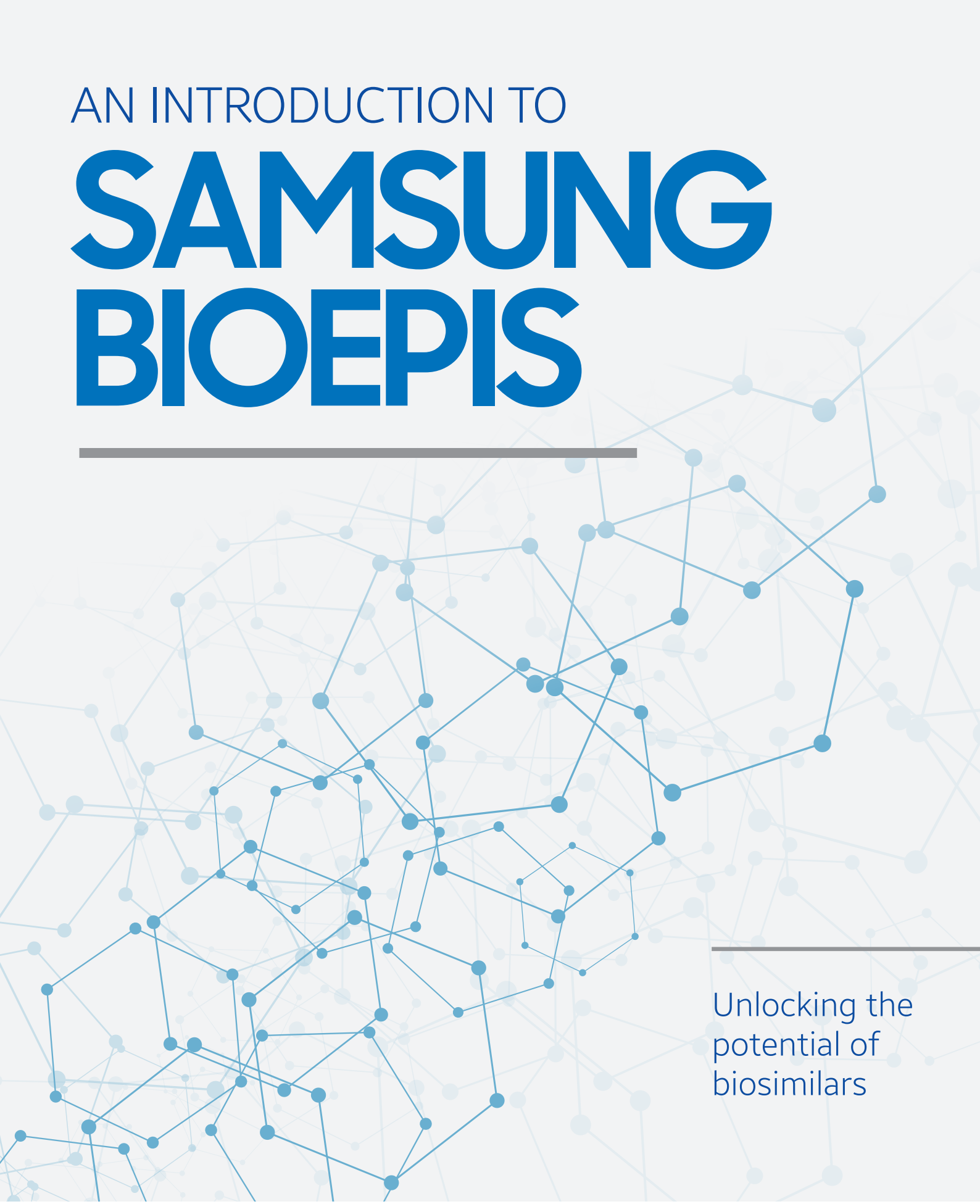
AN INTRODUCTION TO

SAMSUNG BIOEPIS



Unlocking the potential of biosimilars

SAMSUNG
BIOEPIS

We use **innovative science** to unlock the **healthcare of the future.**

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WHO WE ARE

A message from
Christopher Hansung Ko,
President & Chief Executive Officer

At Samsung Bioepis, we are relentless in our efforts to speed up and enhance the development of high-quality biosimilars, because we are on a mission to broaden access to life-changing biologic therapies wherever there is an unmet need.

By nurturing a dynamic and diverse workforce, focusing on process innovation and establishing strong partnerships, we have come a long way since our founding in 2012. Five of our biosimilars have been approved and are available around the world and we hope our diverse and rapidly advancing pipeline will continue this momentum in the years to come.

We will continue to apply new thinking to healthcare and use innovative science and technology to unlock the healthcare of the future. Our work has only just begun.

With warm regards,

Christopher Hansung Ko

OUR MISSION

Samsung Bioepis is a biopharmaceutical company dedicated to accelerating access to biologic medicines by bringing high-quality, clinically proven biosimilars to patients who need them.

Our mission is reflected in our name, **bio-epis**; literally meaning life ("**bio**") and science ("**episteme**") in Greek.

We are in a new era of biologic medicines, which are becoming a mainstay of treatment for critical and chronic medical conditions.[i] Yet there remain inequalities in access to biologic therapies,[ii] so we are focusing on the development of a cost-effective alternative – high-quality biosimilars.

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WHY WE FOCUS ON BIOSIMILARS

By increasing access to high-quality medicines, biosimilars can bring value to patients, healthcare professionals, payers and many other stakeholders within the wider healthcare system.

A biosimilar is a biological medicine that is highly similar to an approved biological medicine (the 'reference biologic'). Biosimilars must meet the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines.[iii]

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Biologics will account for 31% of global pharmaceutical sales (by value) by 2024.[iv]

It is estimated that there will be up to $100 billion of potential savings from biosimilars between 2020 and 2024 in the United States.[v]

At Samsung Bioepis, we are confident that biosimilars will continue to positively impact all stakeholders across the world over the coming years through:

1. Expanding patient access:

Biosimilars are helping to broaden patient access to biologic therapies.[vi] We embed 'process innovation' at every stage of the development process, so that we can bring high-quality, cost-effective biologics to patients who need them. We have established world-class commercialization and manufacturing partnerships to meet the demands of healthcare systems across the globe.

2. Greater cost-effectiveness:

While biologics are now considered the gold-standard treatment across many conditions, cost continues to be a significant barrier to access.[vii] Biosimilars can result in savings to health services that can be reinvested to broaden access and build a more sustainable healthcare system.[viii]

3. Driving market competition and innovation:

By increasing market competition, biosimilars have become an important lever for the innovation of next generation biologics. While our focus remains on the development of high-quality biosimilars, we are now taking our first steps into novel biologic development. We are also looking to enhance the patient experience, including through the development of ergonomic autoinjector devices and extended storage conditions for our products.[ix,x]

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OUR HISTORY

Samsung Bioepis was founded in 2012 and is headquartered in Incheon, Korea.

Samsung Bioepis has developed one of the most expansive and rapidly advancing biosimilar medicines portfolios in the industry.

2012

Samsung Bioepis established (as a joint venture between Samsung BioLogics and Biogen) and opens first R&D Center

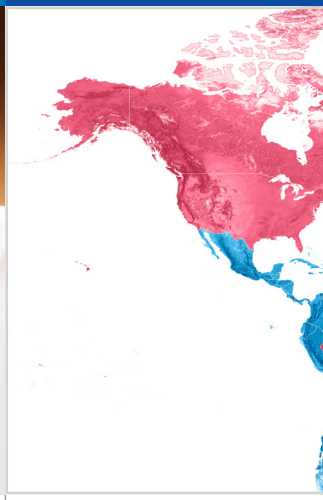
2013

- Samsung Bioepis launches commercialization partnerships with Merck (also known as MSD outside the US and Canada) and Biogen
- Infliximab and etanercept biosimilars approved by Korea's Ministry of Food and Drug Safety (MFDS)

2014

2015

2016



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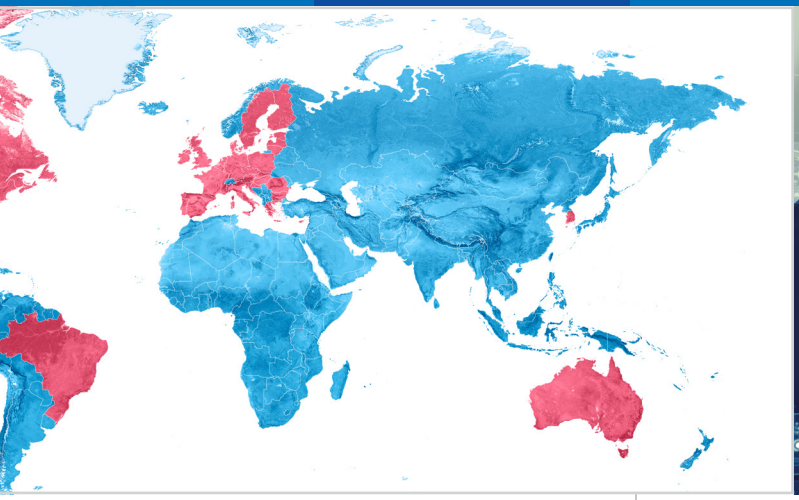
- Infliximab and etanercept biosimilars approved by the European Commission (EC), Australia's Therapeutic Goods Administration (TGA) the Brazilian Health Regulatory Agency (ANVISA) and Health Canada
- Adalimumab and trastuzumab biosimilars approved by the EC and MFDS
- Infliximab biosimilar approved by the U.S. Food and Drug Administration (FDA)
- Samsung Bioepis enters into a risk-sharing partnership with Takeda for the development of novel biologics

- Samsung Bioepis moves into the new office located in Songdo, Korea
- Bevacizumab biosimilar approved by MFDS

2017 2018 2019 2020 2021



- Samsung Bioepis enters into two new partnership agreements with 3SBio and CBC Group (previously known as C-Bridge Capital)/AffaMed Therapeutics in China
- Trastuzumab, etanercept and adalimumab biosimilars approved by the FDA
- Samsung Bioepis expands partnership with Biogen for two ophthalmology biosimilar candidates in the US, Canada, Europe, Japan, and Australia
- Samsung Bioepis' trastuzumab biosimilar becomes the first biosimilar to gain World Health Organization (WHO) prequalification status
- Samsung Bioepis' bevacizumab biosimilar receives EC approval

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A UNITED PASSION FOR HEALTH

Our people are pioneers, chosen for their talent, passion and united vision for improving the lives of patients.

At Samsung Bioepis, we foster a mindset that the best ideas can come from anywhere within our business, so we encourage open innovation at every stage of our employees' careers.

On the job training from day one

Our induction program is as rigorous as our approach to biosimilars development. We make a significant investment in training that allows our people to reach their full potential. Every new employee undergoes a comprehensive training program, including hands-on experience in our labs, to get to the heart of our business and the work we do for patients.

Mentoring scheme

We believe in the power of learning from one another. Every new employee is mentored to accelerate their progress and their mentor also supports their integration into our community.

Health and wellbeing

Caring for the wellbeing of our colleagues is a priority. We offer everything from an in-house fitness facility and pharmacy to private medical screenings and insurance.

Fast facts about our people

Currently at Samsung Bioepis:[1]

900+
employees

53%
have an advanced degree

33
average age

1 Updated as of March 2021

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OUR THERAPEUTIC FOCUS

We apply our smart research and development processes to six therapeutic areas – oncology, immunology, ophthalmology, hematology, gastroenterology, and endocrinology.

Our first-wave biosimilars focus on key therapy areas in immunology and oncology:

Immunology

Immunological diseases such as rheumatoid arthritis and inflammatory bowel disease are growing in prevalence.[xi] Our broad range of high-quality biosimilars is fueling greater access to life-changing treatment for patients in need.

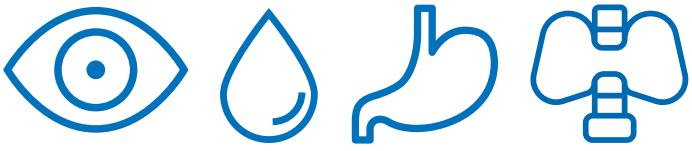
We were the first company to launch biosimilars of the three most prescribed anti-TNF therapies for immunological diseases across Europe: etanercept, infliximab and adalimumab.

Oncology

The number of global cancer deaths is projected to increase by 45% between 2008 and 2030.[xii] This underscores the importance of ensuring that the cost of cancer care is sustainable for healthcare systems and that innovation of new therapies is supported.

We were the first company to launch a trastuzumab biosimilar in Europe. Our bevacizumab biosimilar received EC approval in August 2020 and is currently available in Europe.

Our pipeline is now expanding into new therapy areas:



Ophthalmology Hematology Gastroenterology Endocrinology

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PIONEERS OF RESEARCH AND DEVELOPMENT

We want to enhance the lives of patients through our innovative and pioneering use of science and technology. This includes our pipeline, advanced development platform, optimized clinical development and world-class manufacturing.

Our portfolio

As a world-leader in biosimilars, we have one of the most expansive and rapidly growing portfolios in the industry.

Our five approved biosimilars are:[2]

Samsung Bioepis code	INN	Therapy area
SB4	Etanercept	Immunology
SB2	Infliximab	Immunology
SB5	Adalimumab	Immunology
SB3	Trastuzumab	Oncology
SB8	Bevacizumab	Oncology

We strive for constant innovation and we are putting our passion and expertise to work in our biosimilars pipeline:[3]

Samsung Bioepis code	INN	Therapy area	Status
SB11*	Ranibizumab	Ophthalmology	Filing[4]
SB12	Eculizumab	Hematology	Phase III
SB15*	Aflibercept	Ophthalmology	Phase III
SB16	Denosumab	Endocrinology	Phase III
SB17	Ustekinumab	Immunology	Phase III

*** Phase I clinical trial was waived for SB11 and SB15**

2 Approval status differs according to country/region. Representative example only

3 Updated as of July 2021

4 SB11 has received positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in June 2021. In the United States, it is under review by the U.S. Food and Drug Administration (FDA)

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Our long-term vision is to investigate novel biologics to address the unmet needs of patients without viable treatment options. We have entered into a risk-sharing partnership with Takeda for the development of novel biologics. Through this partnership, our two companies will co-fund and collaboratively develop innovative therapies which will provide meaningful value to patients.
Our first therapeutic candidate is for the treatment of severe acute pancreatitis:

Samsung Bioepis code	INN	Therapy area	Status
SB26 / TAK-671	Ulinastatin-Fc Fusion Protein	Gastroenterology	Phase I

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PIONEERS OF RESEARCH AND DEVELOPMENT

Our advanced development platform

Through process innovation, we have initiated an advanced development platform which drives extensive analysis, risk management and rigorous quality control at each step of the development process, from pre-clinical to large scale manufacturing.

Establishing these processes has enabled us to produce high-quality biosimilars in a shorter time period, while minimizing risks at each stage. Below are some of the measures we implement to improve our development process:

1. Quality by Design (QbD)

Quality by Design is a systematic approach where the biosimilar development process is designed with pre-determined goals based on a risk assessment.

2. Critical Quality Attributes

In the development of biosimilars, we implement a rigorous analysis of the reference medicine so that the characteristics that determine the quality, efficacy and safety of a biosimilar can be defined. These are known as the Critical Quality Attributes (CQAs).
We are constantly learning more about how these CQAs contribute to clinical outcomes. This research can help to raise the bar in quality and efficacy of biologic medicines – we can ensure that CQAs are routinely monitored and controlled within a specified limit. With advancements in biotechnology and analytical methods, biosimilar developers are contributing to science with new discoveries about the critical attributes of biologics.

3. Failure Modes and Effects Analysis (FMEA)

As part of our process innovation, we implement a risk management approach based on scenario planning and simulations. Based on knowledge gained from previous development projects, we build a robust mitigation strategy that allows us to plan for possible risks and minimize failures at each stage of the development process.

4. Tollgate system

Tollgate is a quality control system which allows us to assess whether quality goals are met at each point in the development process. Only the highest-quality molecule that surpasses the quality standards will move to the next stage.

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Optimized clinical development and real-world data generation

We have a robust data generation strategy through clinical development programs and real-world studies to strengthen the body of evidence to support the safety and efficacy of biosimilars.

Global clinical programs

To date, we have successfully conducted over 17 global Phase I-IV clinical trials at 500 sites across over 30 countries.[5] We have been able to maximize cost-effectiveness and reduce the clinical development timelines, allowing us to bring high-quality treatments to patients, faster.

Real-world studies

Together with our commercial partners, we have a range of data generation strategies in place, to increase the body of real-world evidence for the use of biosimilars.

Approximately 35,000 patients have participated in our studies or are included in the registries we support.[6]

World-class manufacturing and supply chain management

At Samsung Bioepis, our aim is to ensure 100% supply continuity for patients. We achieve this by efficiently managing manufacturing and storage sites and working with renowned Contract Manufacturing Organizations (CMO's) across Europe, North America and Asia.

Our manufacturing strategy is established during early stage development in order to ensure commercial supply continuity. Across our portfolio, we have implemented dual sourcing strategy at all stages of manufacturing, which includes securing additional capacity from a second CMO. At all stages, we closely monitor inventory levels to accommodate market dynamics and fluctuation in demand.

5 Updated as of January 2020. Samsung Bioepis Data on File

6 Updated as of January 2020. Samsung Bioepis Data on File

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IMPROVING ACCESS THROUGH STRATEGIC PARTNERSHIPS

We collaborate with partners to broaden the availability of our high-quality biosimilars to patients across the world.

Global Commercialization Partnerships

We have an extensive sales and marketing network through our global commercialization partnerships with Biogen and Organon.

Biogen is a biotech pioneer with over 40 years of experience of developing, manufacturing and commercializing advanced biologic medicines, that is underpinned by a reliable supply chain record. Organon, a global healthcare company formed through a spinoff from Merck, also known as MSD outside of the US and Canada, works with customers and operate in more than 140 countries to increase patient access to treatments.

Local Commercialization Partnerships

Local partnerships are helping us to expand our business to help patients across multiple countries.

We have established partnerships with 3SBio and CBC Group/AffaMed Therapeutics for the clinical development, regulatory registration and commercialization of our products in China. For Hong Kong and Taiwan, we have a partnership with Mundipharma.

Through the Productive Development Partnership (PDP) we have with Bionovis and Bio-Manguinhos, we have been supplying our etanercept biosimilar to Brazil's Ministry of Health while also contributing to the development of the local biopharmaceutical industry by transferring manufacturing technology to our local partners.

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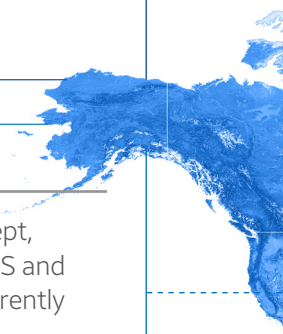
PROVIDING BIOSIMILARS ACROSS THE WORLD

Our innovative research and development platforms, combined with manufacturing and partnerships has helped us to establish a global footprint, so we can provide high-quality biosimilars to those who need them most.

Our biosimilars are available across five continents (Asia, Europe, North America, Oceania, and South America).

Europe

- We launched our first biosimilar in Europe in 2016, and now have five biosimilars (infliximab, etanercept, adalimumab, trastuzumab, bevacizumab) available in Europe
- In Europe, our immunology biosimilars have been used to treat approx. 240,000 patients[7]



North America

- We have four biosimilars (infliximab, etanercept, adalimumab, trastuzumab) approved in the US and two of them (infliximab, trastuzumab) are currently available
- Since launch, the uptake of our infliximab biosimilar is increasing, partly due to the Department of Veteran Affairs tender which was secured in 2018
- We have three biosimilars (infliximab, etanercept, adalimumab) approved and launched in Canada

South America

- Three biosimilars (infliximab, etanercept and trastuzumab) are approved in Brazil and two of them (etanercept, trastuzumab) are currently available
- Our etanercept biosimilar was the first anti-TNF biosimilar to become available in Brazil in September 2019

7 Updated as of March 2021

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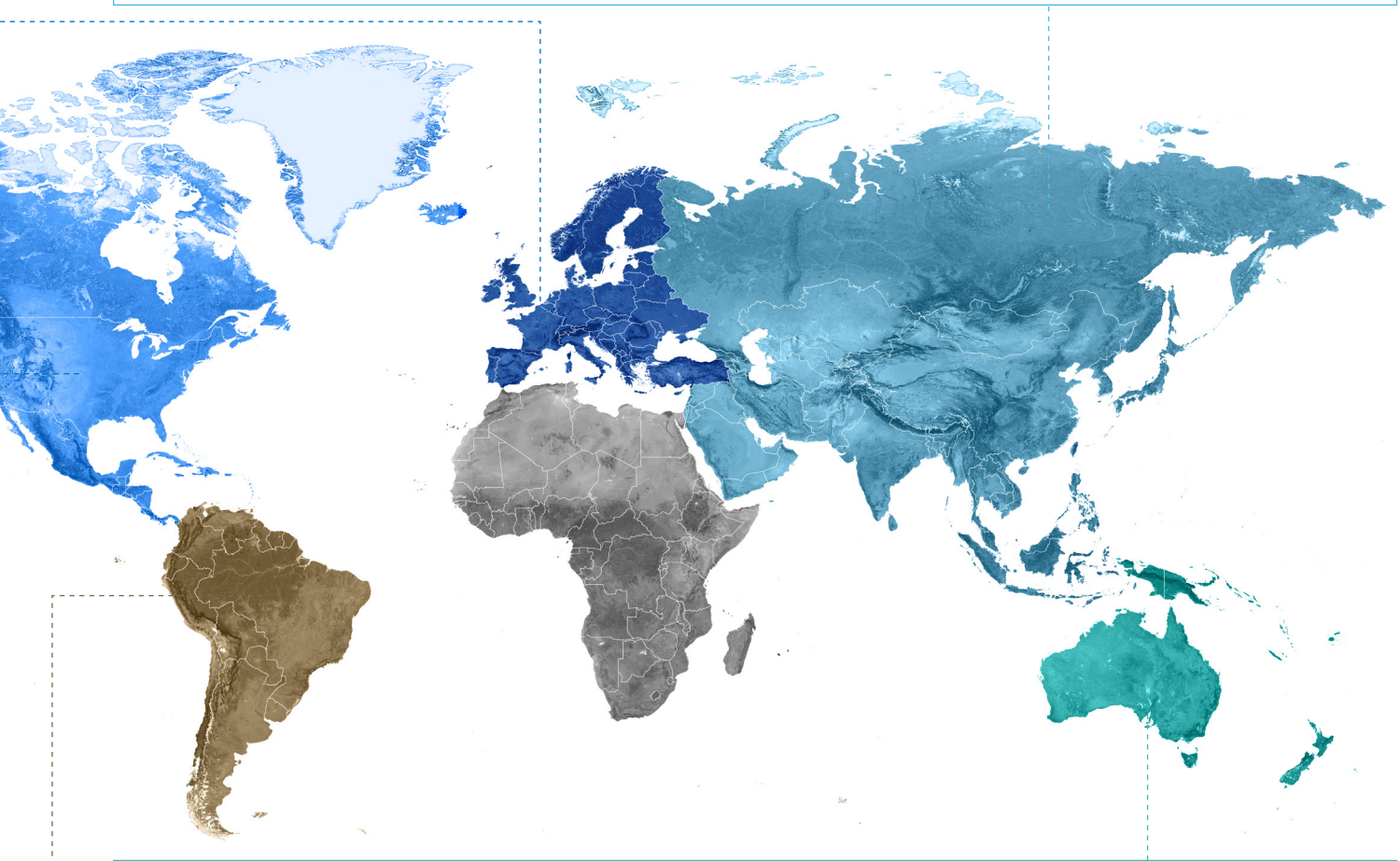
Asia

- We have partnership agreements with 3SBio and CBC Group/AffaMed Therapeutics in China
- We have a partnership agreement with Mundipharma in Hong Kong and Taiwan
- We have five approved biosimilars (infliximab, etanercept, adalimumab, trastuzumab, bevacizumab) in Korea, and three of them (infliximab, etanercept, trastuzumab) are currently available



Oceania

- Four biosimilars (infliximab, etanercept, adalimumab, trastuzumab) are approved and launched in Australia
- Our etanercept biosimilar is approved in New Zealand

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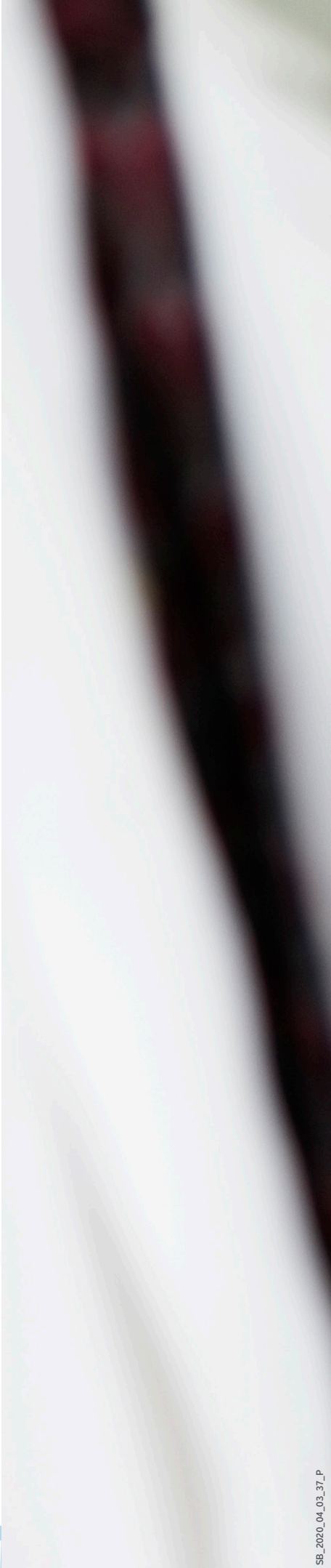

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Every day we put our **passion to work** and strive for **constant innovation** to support patients in need.

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For more information about us, visit

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